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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/24/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/654,223

Applicant(s)

Dedieu

Examiner

Dave Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on December 16, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 20-25 is/are rejected.
- 7) ☒ Claim(s) 17-19 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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The specification has been amended, claims 2-14 have been amended, claims 17-25 have been added by the amendment filed December 16, 2002. As such, the non-compliance letter dated 1/31/03 has been vacated by the examiner.

Claims 1-25, to which the following grounds of rejection remain and/or are applicable, for examination, are pending for examination.

The specification is objected because the first paragraph of the specification regarding the cross-reference information needs to be updated to reflect the relationship between this reissue application and the issued patent

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 20-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are readable on a genus of isolated naturally occurring promoters, synthetic promoters, or chimeric promoters whose transcriptional activity is activated by an Epstein-Barr Virus antigen (EBV

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antigen) or a papilloma virus antigen.

The specification at the time the invention was made only provides sufficient description of only one species of the chimeric promoter, which comprises the EBNA1 response element (EBNA1-RE) fused upstream of a viral promoter, e.g., EBNA1-RE/TP1 (column 7).

However, the claims encompass a genus of naturally occurring, synthetic, or chimeric promoters that must possess the property of being able to be activated transcriptionally by any EBV antigen or any papilloma virus antigen. Since the claimed genus encompasses other chimeric sequences yet to be discovered, and since the disclosure only provides a sufficient description of a chimeric promoter EBNA1-RE-viral promoter. Weighing all factors, 1) disclosure of only the chimeric promoter EBNA1-RE/TP1, 2) the breadth of the claim as reading on genomic regulatory sequences and man-made regulatory sequences yet to be discovered, and 3) No specific drawings and structures that would lead one skilled in the art to envision a representative number of species of chimeric promoter modules, one skilled in the art would not recognize from the disclosure that application was in possession of the genus of promoter sequences, which are essential features of the presently pending claims.

Claims 1-16, 20-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

A replication defective recombinant adenovirus comprising a heterologous DNA sequence under the control of the chimeric promoter which is inducible by an Epstein-Barr virus antigen or by a papilloma virus antigen, wherein the chimeric promoter comprises the EBNA1 response element (EBNA1-RE) fused upstream of a viral promoter.

The specification is not enabling for any other claimed embodiment as embraced by the presently pending claims.

The specification does not enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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When given their broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including unspecified regulatory sequences obtained from genomic sequences and/or man-made synthesis. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of nucleic acid elements as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not know how to make and use the claimed invention as generically so that it would operate as intended.

Applicant's response (pages 6-9) has been considered by the examiner, but is not found persuasive because of the reasons set forth in the stated rejection and because of the following reasons:

Applicant mainly asserts that by describing the involvement of the E6 HPV antigen, EBV EBNA1 and EBNA2 antigen during tumor formations, and that the antigens stimulate induces the activity of an expression signal, applicant complies with the written description requirement. In response, the examiner maintains that the issues raised in the written description rejection are not that applicant does not describe the involvement of the E6 HPV antigen, EBV EBNA1 and EBNA2 antigen during tumor formations, nor are applicant's contemplation of employing any expression signal that is inducible by an EBV antigen or by a papilloma virus antigen. The issue is rather that the claimed invention embraces the make and use of any expression signal which must exhibit the ability of being an EBV inducible promoter or a papilloma virus antigen-inducible promoter, which expression signal is clearly claimed as being a genus of EBV inducible promoters or a papilloma virus antigen-inducible promoters. As set forth in the stated rejection, the

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evidentiary support for the lack of sufficient description of a representative number of species of the genus of EBV inducible promoters or a papilloma virus antigen-inducible promoters is the fact that the as-filed specification only describes one species of a chimeric promoter, which composed mainly of the EBNA1 response element (EBNA1-RE) fused upstream of a viral promoter. As such, the examiner maintains that the claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming a genus of expression signal sequences and/or chimeric promoters that must possess the biological property as contemplated by applicant's disclosure, without defining what means will do so other than the disclosure of the species of the EBNA1 response element (EBNA1-RE) fused upstream of a viral promoter is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived, since there is no prior art of record, drawings, figures, or any part of the disclosure provides any description or the essential structure of a representative number of species of expression signal sequence that must exhibit applicant's intended application or claimed property, the intended application or the property of which are deemed essential to the presently claimed invention. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of chimeric promoter with the specific biological activity on the basis of the disclosure as claimed, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed. Thus, the examiner maintains that not only

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applicant does not provide a sufficient description of any papillomavirus antigen-inducible promoter, of any EBV inducible promoter, applicant also does not provide sufficient description of a representative number of EBNA1 or EBNA2 inducible chimeric promoter. The only described species of a chimeric promoter, which comprises the EBNA1 response element (EBNA1-RE) fused upstream of a viral promoter, is not sufficient to overcome the written description requirement, particularly in view of the reasons set forth above.

With respect to the enablement rejection under 112, first paragraph, applicant mainly asserts that the office action provides no analysis of the *Wand* factors, and that it is not sufficient to maintain the rejection under 35 USC 112, first paragraph.

The examiner maintains that the stated rejection clearly states:

Since the claimed invention is not supported by a sufficient written description (for possessing of the genus of nucleic acid elements as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not know how to make and use the claimed invention as generically so that it would operate as intended.

In view of the lack of written description for claiming a genus of expression signal sequences as claimed, the examiner maintains that the lack of a sufficient description as set forth above, which leads to the lack of sufficient guidance and/or working examples to enable the full breadth of the claimed invention, a person skilled in the art including those having a relatively high skill in the art of recombinant vectors, would not know how to make and use, without undue experimentation, the claimed invention as broadly claimed. As such, the examiner has provided sufficient evidence to show that the *Wand* Factors other than the relatively high skill those skilled in the art have not been met by the as-filed application.

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Claims 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN **SIX MONTHS** FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen  
Primary Examiner  
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DAVE T. NGUYEN  
PRIMARY EXAMINER